

K961728

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VI. 510(k) Summary of Safety and Effectiveness

A. Name and Address

This Summary of Safety and Effectiveness is being submitted by Nobelpharma USA, Inc., 777 Oakmont Lane, Suite 100, Westmont, IL 60559. Their telephone number is (708) 654-9100. The contact person will be the Director, Regulatory Affairs. This summary was prepared on May 1, 1996.

B. Name of the Device

This device is known as an abutment to an endosseous implant with the trade name BRÅNEMARK SYSTEM® MirusCone Abutment System. This submission is a modification to a previously cleared device, K944964.

C. The Predicate Product

The predicate product used in this Premarket Notification is the previous version of the same device, MirusCone Abutment System, K944964.

D. Description of the Device

The Nobelpharma MirusCone Abutment System is an abutment used with an endosseous implant which is implanted in the upper or lower jaw bone. The abutment has a lower profile (vertical height) for use when the dentist desires a lower profile abutment. The only modifications to the device are the broadening and narrowing of the base and external diameters of the abutments; and broadening and narrowing of the diameters of the abutment screws, adding two series of abutments fitting the larger and smaller diameters of fixture previously cleared.

E. Intended Use of the Device

The Nobelpharma MirusCone Abutment System is intended to be used in edentulous patients as an anchor to support a prosthesis.

F. Comparison of Technological Characteristics

The technological characteristics between the modified version of the MirusCone Abutment and the earlier version are identical. The only changes are minor dimensional changes to the diameters of the abutment, the abutment screw and the prosthetic screw.